DOCKET NO.: MPCI-0031

Application No.: 09/690,974

1

Office Action Dated: February 6, 2003

This listing of claims will replace all prior versions, and listings, of claims in the application.

**PATENT** 

## **Listing of Claims:**

Please amend claims 1, 12, 22, 28 and 34 and withdraw claims 37-42 from consideration as follows:

1. (Presently Amended) A drug dosage form prepared by compression techniques comprising:

a compound thyroid hormone susceptible to moisture induced degradation, and

at least one pharmaceutically acceptable excipient <u>having equilibrium</u> moisture, the drug dosage form prepared under conditions of low compression of up to 5,000 psi/g.

2. (Original) The drug dosage form of claim 1 comprising a capsule.

3. (Original) The drug dosage form of claim 1 comprising a capsule formed of hydroxypropyl methylcellulose.

4. (**Original**) The drug dosage form of claim 1 wherein the compound is contained in solid form within a capsule.

5. (Original) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 10,000 psi/g.

6. (Original) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 5,000 psi/g.

7. (**Original**) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 2,000 psi/g.

Page 2 of 11

DOCKET NO.: MPCI-0031

**Application No.:** 09/690,974

Office Action Dated: February 6, 2003

PATENT

8. (Original) The drug dosage form of claim 1 wherein the excipient is hydroxypropyl

methylcellulose, carboxymethyl cellulose, microcrystalline cellulose, amorphous silicon

dioxide, magnesium stearate, starch, sodium starch glycolate, or a combination thereof.

9. (Original) The drug dosage form of claim 1 wherein the excipient has a residual

moisture content of less than about 10% by weight.

10. (Original) The drug dosage form of claim 1 exhibiting improved stability to

moisture-induced degradation of the compound as compared with a tabletted form of the

compound.

11. (Original) The drug dosage form of claim 1 comprising a unit dosage form.

12. (Presently Amended) A drug dosage form prepared by compression techniques

comprising for-a compound susceptible to moisture-induced degradation comprising the

compound admixed with a substantially non-volatile, pharmaceutically acceptable oil, the

drug dosage form prepared under conditions of low compression of up to 5,000 psi/g.

13. (Original) The drug dosage form of claim 12 wherein the oil is an animal or

vegetable oil.

14. (Original) The drug dosage form of claim 12 wherein said oil is olive, corn, peanut,

nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.

15. (Original) The drug dosage form of claim 12 wherein the oil is a mineral oil or

silicone oil.

**PATENT** 

**DOCKET NO.:** MPCI-0031 **Application No.:** 09/690,974

Office Action Dated: February 6, 2003

16. (**Original**) The drug dosage form of claim 12 wherein the compound - oil admixture is present within a capsule.

- 17. (Original) The drug dosage form of claim 12 wherein the compound oil admixture is present within a soft shell capsule.
- 18. (**Original**) The drug dosage form of claim 12 wherein the compound oil admixture is present within a specially sealed hard-shell capsule.
- 19. (Original) The drug dosage form of claim 12 wherein at least some of the compound oil admixture is adsorbed on a pharmaceutically acceptable excipient.
- 20. (Original) The drug dosage form of claim 12 wherein the excipient having the compound oil admixture adsorbed thereupon is within a capsule.
- 21. (Original) The drug dosage form of claim 12 wherein the excipient having the compound oil admixture adsorbed thereupon is within a tablet.
- 22. (Presently Amended) A drug dosage form prepared by compression techniques comprising:

  for a compound susceptible to moisture-induced degradation comprising the drug, and

a pharmaceutically acceptable excipient admixed with a substantially non-volatile, pharmaceutically acceptable oil,

wherein the drug dosage form is prepared under conditions of low compression of up to 5,000 psi/g.

23. (Original) The drug dosage form of claim 22 wherein the oil is an animal or vegetable oil.

Page 4 of 11

**PATENT** 

**DOCKET NO.:** MPCI-0031 **Application No.:** 09/690,974

Office Action Dated: February 6, 2003

24. (Original) The drug dosage form of claim 22 wherein said oil is olive, corn, peanut, nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.

- 25. (Original) The drug dosage form of claim 22 wherein the oil is a mineral oil or silicone oil.
- 26. (**Original**) The drug dosage form of claim 22 wherein the drug and the excipient oil admixture are present within a capsule.
- 27. (**Original**) The drug dosage form of claim 22 wherein the drug and the excipient oil admixture are present within a tablet.
- 28. (Presently Amended) A drug form prepared by compression techniques comprising a compound susceptible to moisture-induced degradation admixed with a first pharmaceutically acceptable oil together with a pharmaceutically acceptable excipient admixed with a second pharmaceutically acceptable oil,

wherein the drug form is prepared under conditions of low compression of up to 5,000 psi/g.

- 29. (Original) The drug dosage form of claim 28 wherein the first and the second pharmaceutically acceptable oils are, independently, an animal or vegetable oil.
- 30. (Original) The drug dosage form of claim 28 wherein the first and the second pharmaceutically acceptable oils are, independently, olive, corn, peanut, nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.
- 31. (Original) The drug dosage form of claim 28 wherein the first and the second pharmaceutically acceptable oils are, independently, a mineral oil or silicone oil.

DOCKET NO.: MPCI-0031 PATENT

**Application No.:** 09/690,974

Office Action Dated: February 6, 2003

32. (Original) The drug dosage form of claim 28 wherein the compound - oil admixture and the excipient - oil admixture are present within a capsule.

33. (**Original**) The drug dosage form of claim 28 wherein the compound - oil admixture and the excipient - oil admixture are present within a tablet.

34. (Presently Amended) A drug dosage form comprising:

a compound susceptible to moisture induced degradation, and at least one pharmaceutically acceptable hydrophobic powder, wherein the drug dosage form is prepared under conditions of low compression of up to 5,000

psi/g.

35. (**Original**) The drug dosage form of claim 34 wherein the hydrophobic powder is triturated directly with the compound.

36. (Original) The drug dosage form of claim 34 wherein the hydrophobic powder is magnesium stearate.

37. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound which has not been processed employing high compression.

- 38. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound admixed with a substantially non-volatile, pharmaceutically acceptable oil.
- 39. (Withdrawn) The method of claim 38 wherein the compound oil admixture is present within a capsule.

**DOCKET NO.:** MPCI-0031 **Application No.:** 09/690,974

Office Action Dated: February 6, 2003

**PATENT** 

40. (Withdrawn) The method of claim 38 wherein the compound - oil admixture is adsorbed on a pharmaceutically acceptable excipient.

- 41. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound and a pharmaceutically acceptable excipient admixed with a substantially non-volatile, pharmaceutically acceptable oil.
- 42. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound and at least one pharmaceutically acceptable hydrophobic powder.

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